REMARKS

Claims 1-40 were pending in the application. Claims 3, 6, 17-23, and 36-40 have been canceled without prejudice as being directed to a non-elected invention and claims 1, 2, 5, 7 and 10 have been amended. Support for the amendments to the claims can be found throughout the specification as filed. Accordingly, claims 1, 2, 4, 5, 7-16, and 24-35 will be pending upon entry of the present amendment.

Support for the amendment to the specification can be found at, for example, pages 9 and 21, and page 35, lines 25-28 of the specification, where the entire contents of Zhou, et al. ((1999) Cell Mol. Life Sci. 56:788-806) and U.S. Patents 5,952,647 and 5,972,697 were expressly incorporated into the present application by reference.

No new matter has been added. Amendment and/or cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to more particularly point out and distinctly claim the subject matter that Applicant believes to be his invention in order to expedite prosecution. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

Objections to the Claims

Claims 1-2, 4, 7-8, 10, and 24-35 were objected to because the claims are drawn, in part, to non-elected inventions, i.e., methods for facilitating the diagnosis of prostate cancer using mRNA levels of Pin1. Applicants have amended the claims to be directed to methods using only Pin1 polypeptides, thereby rendering this objection moot.

Claims 1-2, 4-5, 7-16 and 24-35 were objected to for the use of the abbreviated language "TDPCA" in claims 1-2 and 24-37. Applicants respectfully point out that page 8, lines 17-26 of the specification provide the definition of this term. However, in the interest of clarity, claim 1 has been amended to indicate the meaning of the term "TDPCA," thereby rendering this objection moot.

Claims 5, 7, and 10 were objected to as being dependent on non-elected claim 3. Accordingly, claims 5, 7 and 10 have been amended so as to no longer depend on claim 3, thereby rendering this objection moot.

Claims 9, 11-12, and 15-16 were objected to because it is not clear in claim 5 whether "a fragment thereof" refers to a fragment of an antibody to Pin1 or a fragment of Pin1. Applicants

have amended the claims to clarify that the fragments in question are fragments of an antibody to Pin1, e.g., fragments such as the ones disclosed at page 22, line 32 through page 23, line 7 of the specification.

Lastly, claim 33 was objected to because "it is not clear what a 'percent free prostate specific antigen between about 15 and about 25 [means].'" Applicants respectfully point out that the term in question is intended to mean the percent of free, i.e., unbound, PSA out of the total amount of PSA. For example, the specification teaches at page 13, lines 25-34 and in Table 2 at page 14 examples of bound PSA, i.e., PSA bound to α1-antichymotrypsin (PSA-ACT) or α2-macroglobulin.

Based on the foregoing, Applicants respectfully request reconsideration and withdrawal of the foregoing objections.

Rejections Under 35 U.S.C. 112, First Paragraph

Claims 1-2, 4-5, 7-16 and 24-35 were rejected as failing to comply with the enablement requirement on the ground that

> [o]ne cannot extrapolate the teaching in the specification to the enablement of the claims, because one would not know how to make the invention, due to the lack of disclosure in the claims and in the specification [of] the actual sequence structure of Pin1.

Applicants respectfully submit that the specific disclosure of the sequence of Pin1 is not necessary for the enablement of the claimed invention. Pin1 is a recognized term in the art, the polynucleotide and polypeptide sequences of which have been widely published. Therefore, the skilled artisan would not have to rely "solely on the GenBank sequence accession number" as asserted at page 5 of the Office Action because the sequences of Pin1 are available from a number of sources. Accordingly, one of ordinary skill, given this term in the context of the instant application, would readily understand how to obtain Pin1 for use in the claimed invention.

Moreover, the amino acid and nucleic acid sequences of Pin1 were disclosed in U.S. Patent Nos. 5,952,647 and 5,972,697 (cited at page 21, lines 34-35 of the specification), as well as in Zhou et al. (1999) Cell Mol. Life Sci. 56:788-806 (cited at page 9, line 12 of the specification). These publications were expressly incorporated in the present specification at

page 35, lines 25-28. Accordingly, Applicants have amended the application to include the amino acid sequence of Pin1 (see the amendment at page 9 of the specification).

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejection.

Claims 1-2, 4-5, 7-16 and 24-35 were rejected as not being enabled on the ground that the term "Pin1" encompasses both the wild type and variants of Pin1, and the specification does not disclose how to make variants of the Pin1 polypeptide. Applicants disagree. However, in the interest of expediting prosecution, and in no way acquiescing to the Examiner's rejection, the claims have been amended to be directed to ***human*** Pin1. Human Pin1 is a polypeptide with a defined sequence, i.e., the sequence incorporated at page 9 of the specification by the instant amendments.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejection.

Claims 5, 11-12, and 15-16 were rejected on the ground that, "the claims are not enabled for a method for facilitating the diagnosis of cancer in a subject, using an antibody to 'a fragment of Pin1.'"

Applicants respectfully submit that the claims as amended clarify that the invention is directed to the use of antibodies, or fragments of antibodies, to Pin1.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejection.

Claims 5, 11-12, and 15-16 were further rejected on the ground that "the claims are not enabled for a method for facilitating the diagnosis of cancer in a subject, by comparing the amount of an anti-Pin1 antibody bound to a test sample to a 'predetermined base level'" because "there is no definition of a predetermined base level."(Office Action at page 9).

Applicants respectfully traverse this rejection. Applicants believe that one of ordinary skill in the art would find the claims to be fully enabled by the specification as written. However, in the interest of expediting prosecution, Applicants have amended the claim to recite "the amount of Pin1 in a normal sample" rather than a "predetermined base level." Support for the amendment to claim 5 can be found at, for example, page 8, lines 6-12 of the specification

where the specification teaches how one of skill in the art would determine the level of Pin1 in a normal, i.e., non-cancerous, sample.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejection.

SUMMARY

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this statement. However, if a fee is due, please charge our Deposit Account No. 12-0080, under Order No. PTZ-007 from which the undersigned is authorized to draw.

Dated: January 18, 2005

Respectfully submitted,

By _____

Cynthia L. Kanik, Ph.D.
Registration No.: 37,320
LAHIVE & COCKFIELD, LLP
28 State Street
Boston, Massachusetts 02109
(617) 227-7400
(617) 742-4214 (Fax)
Attorney/Agent For Applicant